

### **REMARKS**

Claims 1, 3-12, 14-16, and 19-36 are pending. Claims 1, 3-12, 14, 16, 19-28, 30-32 and 34 are allowed. Claims 15, 29, 33, 35, and 36 are rejected. Claims 30 and 34 are objected to. Claims 3, 4, 14, 15, 29, 31, and 33 are amended in this paper.

Claims 3, 14, 29, and 31 have been amended to recite that the “sequence” rather than the “polypeptide” is a portion of INGAP. This is consistent with the language of the claims which recites that the “polypeptide comprises a sequence.” Thus this amendment is consistent with and clarifies the original meaning of the claim. See also column 5, lines 1-7.

Claims 4 and 15 have been amended to recite a first and second sequence that form the fusion polypeptide. This clarifies and makes consistent the claim language. In addition the claim has been amended to recite that the first sequence has immunogenic activity. Previously the claims did not specify which portion of the fusion protein had the activity. This is supported at column 7, lines 32-35 and lines 53-58.

Claims 29 and 33 have been amended to recite that the portion of the INGAP protein is “capable of stimulating  $\beta$  cell regeneration of pancreatic ductal cells.” This is supported at column 7, lines 32-35 and lines 53-58.

It is respectfully submitted that no new matter has been added by these amendments. The amendments were not presented earlier because the Applicants believed that their previous response was sufficient to place the claims in condition for allowance.

The Rejection of Claim 15 under 35 U.S.C. §112, second paragraph

Claim 15 stands rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants respectfully traverse the rejection of claim 15.

The Final Office Action states that claim 15 is indefinite because one cannot discern whether the INGAP or the second polypeptide provides beta cell stimulatory activity. Paper No. 06032004, page 3, second full paragraph. Claim 15 has been amended to recite that the first sequence, *i.e.*, the sequence of amino acids of INGAP “is capable of stimulating  $\beta$  cell regeneration of pancreatic ductal cells.” Claim 15 now clearly indicates which portion of the fusion polypeptide provides the stated biological activity. Claim 4 has been similarly amended to address this issue.

Applicants respectfully request withdrawal of the rejection.

The Rejection of Claims 29 and 33 under 35 U.S.C. §112, first paragraph

Claims 29 and 33 stand rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The PTO asserts that a protein must be defined by both structure and function. Paper No. 06032004, page 3, last paragraph. Applicants respectfully traverse the rejection of claims 29 and 33.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555,

1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991). Descriptions of genetic material can meet the written description requirement by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 323 F. 3d 956, 964, 3 U.S.P.Q.2d (BNA) 1609, 1613 (Fed. Cir. 2002).

While Applicants do not believe that structure and function are required to fully describe a protein under the current law, to expedite prosecution they have amended claims 29 and 33 to recite that the portion of INGAP is “capable of stimulating  $\beta$  cell regeneration of pancreatic ductal cells.” Thus the claims as amended recite a polypeptide with a structure (at least 15 consecutive amino acids of SEQ ID NO: 2) coupled with a function (the capability to stimulate  $\beta$  cell regeneration of pancreatic ductal cells).

Applicants respectfully request withdrawal of the rejection.

#### The Objections to Claims 35 and 36.

Claims 35 and 36 are objected to as being substantially duplicative of allowed claims 31 and 32. Applicants respectfully traverse the objection.

Allowed claims 31 and 32 recite the term “comprising,” whereas claims 35 and 36 recite the term “consisting of.” “Comprising” and “consisting of” are transitional phrases which define the scope of a claim with respect to unrecited additional components. Thus transitional phrases impart substantial meaning to a claim. The transitional term “comprising” is inclusive or open-

ended and does not exclude additional, unrecited elements or method steps. *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368, 66 U.S.P.Q.2d 1631, 1634 (Fed. Cir. 2003). Additional unrecited elements may be added and still form a polypeptide within the scope of claims 31 and 32.

In contrast, the transitional term “consists of” excludes elements from the polypeptide which are not specified in the claim. *In re Gray*, 53 F.2d 520, 11 U.S.P.Q. 255 (C.C.P.A. 1931).

The substantial difference in the scope between claims 31 and 32 and claims 35 and 36 is sufficient to overcome an objection based on substantial duplication of claims. Indeed, the Final Office Action cites a section of the Manual of Patent Examining Procedure that explicitly states that “court decisions have confirmed applicant’s right to restate (*i.e.*, by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough.” M.P.E.P. § 706.03(k). See also *Application of Gemassmer*, 326 F.2d 802, 810 (C.C.P.A. 1964).

Applicants respectfully request withdrawal of the objection.

#### The Rejection of Claims 35 and 36 under 35 U.S.C. §112, second paragraph

Claims 35 and 36 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. Applicants respectfully traverse the rejection of claims 35 and 36.

The test for definiteness under 35 U.S.C. §112, second paragraph, is whether “those skilled in the art would understand what is claimed when the claim is read in light of the specification.” *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986). The Final Office Action urges that in claims 35 and 36

the closed language “consists” is inconsistent with the open language “at least 15 amino acids.”

Paper No. 06032004, page 4, fourth full paragraph. Applicants respectfully traverse.

Independent claim 35 recites:

A pharmaceutical composition comprising **a polypeptide which consists of a portion of islet neogenesis associated protein (INGAP protein) of at least 15 consecutive amino acids** shown in SEQ ID NO: 2, wherein said polypeptide is capable of stimulating  $\beta$  cell regeneration in pancreatic ductal cells.

(Emphasis added.) The claim term “which consists” modifies the phrase that directly precedes it: “a polypeptide.” The claim term “of at least 15 consecutive amino acids” modifies the phrase that directly precedes it: “a portion of islet neogenesis associated protein.” Thus, the polypeptide contains no elements other than the portion because the polypeptide consists of a portion. The portion is at least 15 consecutive amino acids shown in SEQ ID NO: 2. The term “at least 15 consecutive amino acids” is not inconsistent with the term “consists of” because they modify different terms.

Moreover, the term “of at least 15 consecutive amino acids shown in SEQ ID NO:2” is not open-ended because SEQ ID NO:2 has a finite number of amino acid residues. Thus the recitation in claim 35 of the closed language “consists” is congruent with the recitation of “at least 15 amino acids” because they modify different claim terms and because the latter term is not open-ended.

Claim 36 is dependent from claim 35, and for the same reason it complies with 35 U.S.C. §112, second paragraph.

Applicants respectfully request withdrawal of the rejection.

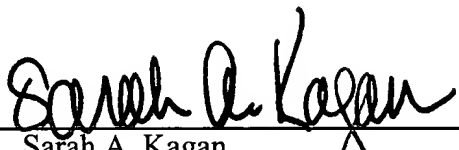
The Objections to Claims 30 and 34

Claims 30 and 34 are objected to as being dependent upon rejected base claims 29 and 33, respectively. The Applicants believe that the current response places claims 29 and 33 in condition for allowance, thus rendering this objection moot.

Applicants respectfully request withdrawal of the objection.

Respectfully submitted,

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